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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/731,499	10/16/1996	JOE W. GRAY	2500.124US1	6686

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/02/2002 98

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/731,499

Applicant(s)

Gray et al

Examiner

Karen Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 6-19, and 23-67 is/are pending in the application.
- 4a) Of the above, claim(s) 24-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6-19, 23, and 45-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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Response to Arguments

1. Claims 1, 6-19 and 23-67 are pending. Claims 24-44 remain withdrawn from consideration. Claims 1, 6-19, 23 and 45-67 are under consideration.
2. The rejection of claims 1, 6, 23, 45 and 46 under 35 U.S.C. 103(a) as being unpatentable over any of accession numbers N32481, N93893, or G11697 in view of Matthews and Kricka is maintained for reasons of record.
3. The rejection of claims 1, 8, 23, 45 and 46 under 35 U.S.C. 103(a) as being unpatentable over any of accession numbers H16953, I6954 or H12950 in view of Matthews and Kricka is maintained for reasons of record.
4. The rejection of claims 1, 10, 23, 45 and 46 under 35 U.S.C. 103(a) as being unpatentable over accession number H40682 in view of Matthews and Kricka is maintained for reasons of record.
5. The rejection of claims 1, 12, 23, 45 and 46 under 35 U.S.C. 103(a) as being unpatentable over any of accession numbers G27410 or G25553 in view of Matthews and Kricka is maintained for reasons of record.
6. The rejection of claims 1, 14, 23, 45 and 46 under 35 U.S.C. 103(a) as being unpatentable over accession number N78571 in view of Matthews and Kricka is maintained for reasons of record.
7. The rejection of claims 1, 16, 18, 23, 45 and 46 under 35 U.S.C. 103(a) as being unpatentable over accession number N70546 in view of Matthews and Kricka is maintained for reasons of record.
8. The rejection of claims 1, 18, 23, 45 and 46 under 35 U.S.C. 103(a) as being unpatentable over accession number WO5407 in view of Matthews and Kricka is maintained for reasons of record.

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9. Applicant argues that the issue is not whether labeling of nucleic acids is known, but rather what specific teaching would motivate one of skill in the art to radiolabel the claimed polynucleotides. This has been considered but not found persuasive as detailed motivation was set forth in all the 103(a) rejections in view of Matthews and Kricka in the office action of Paper No. 31. Applicant argues that descriptive information published with an EST sequence does not provide any information about the putative significance of the respective nucleotide sequence. This has been considered but not found persuasive, as the instant claims do not embody functional limitations for the claimed polynucleotides which would exclude the prior art EST sequences.

10. The rejection of claims 1, 6-19, 45, 46 and 58-63 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventors had possession of the claimed invention at the time the application was filed, is maintained for reasons of record. Applicant argues that the written description requirement does not obligate the inventor to reduce to practice all elements of the invention at the time of filing. This is true. However, in order to satisfy the written description requirement in terms of polynucleotide variants, a recitation of a representative number of polynucleotide variants must be disclosed in the specification, or the genus must be described in terms of the required chemically and structural features that would preserve the function of species within the genus. Applicant maintains that the recitation of hybridization defines the nucleic acids in functional terms. This has been considered but not found persuasive. For example, a hexamer can hybridize to the disclosed polynucleotides under stringent conditions, but a function has not been taught for a hexamer. Applicant argues that the issue is whether one of skill in the art could derive the claimed ranges (variants) from the disclosure. This has been considered but not found persuasive, as the claims drawn to variants do not impose the functional limitations of the polynucleotides taught by the specification.

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11. Claims 1, 6-19, 23 and 45-67 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting over co-pending application number 08/785,532.

The rejection is maintained until the time that applicants file a terminal disclaimer. 5,801,021

12. The rejection of claims 1, 6-13, 23, 45-53, 58-60 and 63 under the judicially created doctrine of obviousness-type double patenting over claims 1-9 of USP 5,892,010 is maintained. The rejection is maintained until the time that applicants file a terminal disclaimer.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

December 31, 2001

